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UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF CALIFORNIA

IN RE INCRETIN-BASED THERAPIES PRODUCTS LIABILITY LITIGATION

Case No. 13md2452 AJB (MDD)

DEFENDANTS' REPLY IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT BASED ON PREEMPTION

Date: September 11, 2015
Time: 9:00 am
Courtroom: 3B
Judge: Hon. Anthony J. Battaglia
Magistrate: Hon. Mitchell D. Dembin

INTRODUCTION

Plaintiffs' Oppositions are blind to what makes this case singular for purposes of preemption. FDA undertook (in the words of Plaintiffs' expert, Dr. Alexander Fleming) an "unprecedented" and "very robust" evaluation of the scientific evidence at a time when it was fully aware of and prompted by Plaintiffs' claim that incretin-based therapies cause pancreatic cancer and that the labeling fails to warn of that alleged risk.[1] Then, one year later, FDA concluded both that (i) "*assertions concerning a causal association between incretin-based drugs and pancreatitis or pancreatic cancer, as expressed recently in the scientific literature and in the media, are inconsistent with the current data*" and (ii) "*the current knowledge is adequately reflected in the product information or labeling*."[2] FDA did this in conjunction with the European Medicines Agency ("EMA"), and the two agencies jointly published their conclusions in the *New England Journal of Medicine*.

No previous case involves this combination of (i) FDA's comprehensive review of the scientific evidence, (ii) conducted with knowledge of Plaintiffs' causation and warning claims, and leading to FDA's dual conclusion that (iii) the evidence does not support a causal association and that (iv) the labeling is adequate. This unique combination constitutes clear evidence that FDA would not have approved a pancreatic-cancer warning at any point to date. As Plaintiffs' expert acknowledged, "[i]t would be a little absurd" to think that FDA would say, "'we've looked at all the data, we've done a comprehensive evaluation, we don't think there's any evidence of causal association, but go ahead and add a warning anyway.'"[3]

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[1] Fleming Tr. at 92:13-16 (relevant portions attached as Ex. BB to the 7/17/2015 Declaration of Amy J. Laurendeau ("7/17/2015 Supp. Laurendeau Decl.") [ECF 1215]).

[2] Amy G. Egan *et al.*, *Pancreatic Safety of Incretin-Based Drugs—FDA and EMA Assessment*, N. Engl. J. Med. 370:9, at 796 (Feb. 27, 2014) ("FDA/EMA Assessment") (Exhibit A to the 6/19/2015 Laurendeau Decl. ("6/19/2015 Laurendeau Decl.") [ECF 1163]).

[3] Fleming Tr. 201:21-202:1 (Ex. D to 6/19/2015 Laurendeau Decl.).

FDA's determination that the labeling is adequate is the cornerstone of Defendants' preemption defense. Yet Plaintiffs' MDL and JCCP Oppositions inexplicably never quote, cite, or even acknowledge FDA's conclusion in 2014 that "the *current* knowledge is adequately reflected in the product information or labeling." Instead, Plaintiffs endlessly repeat that FDA's review is ongoing. But FDA's review of the safety of all approved prescription drugs is always ongoing, and it goes without saying that today's scientific conclusions may sometimes require revision in light of new data. If Plaintiffs were correct that ongoing review of safety data by FDA defeats preemption, then impossibility preemption would itself be impossible in the FDA context.

Plaintiffs' Oppositions are also blind to the fact that Defendants' alleged failure to warn occurred *in the past*. Accordingly, the question for purposes of preemption is whether there is clear evidence that FDA would have approved a pancreatic-cancer warning *then*, not whether it would do so in the future. The 2014 Assessment represents FDA's judgment based on the cumulative knowledge about a possible pancreatic-cancer risk to that date. Because Plaintiffs' failure-to-warn allegations concern the labeling in the years leading up to the 2014 Assessment, the Assessment (and FDA's subsequent statements consistent with the Assessment) constitute clear evidence of what FDA would have done at any time before then.

A. Plaintiffs Misconstrue the "Clear Evidence" Test

Wyeth v. Levine. Plaintiffs have grown bolder with time. They now make explicit what they only suggested before—that *Wyeth* and its progeny established two "musts." To satisfy the "clear evidence" standard, according to Plaintiffs, Defendants *must* have submitted a CBE that FDA rejected and *must* have supplied FDA with an analysis of all conceivable scientific data related to the issue. Pls. MDL Opp. at 16-17; Pls. JCCP Opp. at 21-25. But had the Supreme Court intended to establish this bright-line test—or any bright-line test—it would have done so. Instead, as the Ninth Circuit has recognized, the Supreme Court did not define what constitutes "clear

evidence." The only guidance as to what "clear evidence" means is that "the evidence presented in [*Wyeth v.*] *Levine* was insufficient to meet the clear evidence standard."[4]

Plaintiffs cannot be correct that preemption depends upon FDA's rejection of a CBE. After all, the strongest case for preemption should exist when FDA conducts its own comprehensive analysis and deems the current labeling adequate because there is no scientific basis for a different warning. But, in that situation, a manufacturer has no reason at all to submit a CBE; indeed, it would be "a violation of federal law to propose a CBE that is not based on reasonable evidence."[5] It cannot be, therefore, that a manufacturer faces a Hobson's choice—either submit a CBE that is unsupported by reasonable evidence so as to obtain an express FDA denial or forego the possibility of ever mounting a successful preemption defense. Plaintiffs' contention that the manufacturer *must* submit a CBE also overlooks a change in the statutory framework for regulating prescription drugs since *Wyeth*. The Supreme Court in *Wyeth* understandably emphasized the importance of the CBE process because at the time of the contested prescriptions in that case, FDA lacked express statutory authority to compel the manufacturer to strengthen the labeling.[6] In 2007, however, Congress amended the statute to make explicit FDA's power to mandate labeling changes.[7] This augmentation of FDA's authority changes the "clear evidence" analysis.

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[4] *Gaeta v. Perrigo Pharm. Co.*, 630 F.3d 1225, 1235 (9th Cir. 2011); *Schedin v. Ortho-McNeil-Janssen Pharm.*, 808 F. Supp. 2d 1125, 1132 (D. Minn. 2011) ("[T]he *Wyeth* Court did not elaborate on what type of evidence would clearly establish the FDA would not approve a label change.").

[5] *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 392 (7th Cir. 2010).

[6] *Schedin*, 808 F. Supp. 2d at 1131 (in *Wyeth*, at all relevant times "a brand-name manufacturer was the only entity in the trifecta of actors (FDA, the brand-name manufacturer, and the generic) that could strengthen an inadequate label"); *Cross v. Forest Labs.*, 2015 WL 1534458, at *4 n.1 (N.D. Miss. Apr. 6, 2015) ("Prior to 2007, the FDA lacked authority to order drug manufacturers to revise their labels based on safety information made available after the drug's initial approval.").

[7] 21 U.S.C. § 355(o)(4) (2007). Before the amendment, FDA could request or cajole the manufacturer to make labeling changes or conduct post-approval studies but lacked express authority to mandate them short of revoking approval of the drug.

Because FDA lacked post-approval authority to mandate stronger warnings under the pre-2007 statutory regime, its inaction during that time cannot support an inference that FDA would have rejected a CBE containing the stronger warning. But now, when FDA has the statutory power to instruct a manufacturer to change the labeling, its decision indicates that it finds an absence of new safety information. Federal law now empowers the agency to initiate a labeling change for the same reasons and at the same time as it obligates a manufacturer to submit a CBE.[8] The regulatory "trigger" is the same for the manufacturer and FDA; both must take steps to strengthen the labeling if, but only if, there is "reasonable evidence" of a causal association.[9]

Plaintiffs' claim that a manufacturer *must itself* submit an evaluation of the scientific evidence misses the point of *Wyeth*, which is that there must be clear evidence that FDA gave close and informed attention to the risk. Here, there is clear evidence that FDA did just that in the 2014 Assessment. *Wyeth* does not require more: in deciding preemption, the role of the court is not to second-guess FDA's analysis of the scientific evidence, when it is clear that FDA *did* analyze the evidence.

In sum, because FDA now has both (i) statutory authority to mandate labeling changes and (ii) the regulatory obligation to act when the scientific evidence supports a causal association, and because FDA (iii) "employs the same standards to assess whether to mandate a label change and whether to permit a label change," the FDA/EMA Assessment and FDA's subsequent consistent statements are clear evidence that the agency would not have approved a pancreatic-cancer warning, if submitted by any of the Defendants to date.

Post-*Wyeth v. Levine* Cases. Plaintiffs contend that every post-*Wyeth* case (but two) rejects preemption. Pls. MDL Opp. at 7; *see also* Pls. JCCP Opp. at 18-20. But

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[8] Goldkind Rebuttal Rpt. at 6 (FDA "employs the same standards to assess whether to *mandate* a label change and whether to *permit* a label change") (Ex. Z to 6/19/2015 Laurendeau Decl.).

[9] 21 C.F.R. § 201.57(c)(6) (re "Warnings" section of the labeling); § 201.57(c)(7) (re "Adverse Reactions" section: "some basis to believe . . . .").

that contention is misleading, for virtually all these cases involve SSRI anti-depressant medications, and the decisions turn on substantially the same dispositive facts. Those facts are notably different and distinguishable. *First*, unlike here, the sequence of FDA actions reflected a progressive receptivity to strengthening the SSRI warnings from 2003 onward, before the plaintiffs' injuries.[10] *Second*, unlike here, the courts noted that FDA in fact ultimately approved a warning like the one advocated by the plaintiffs. That is, the plaintiffs argued, and the courts agreed, that FDA likely would have approved a stronger warning because, in the end, it did. In *Mason*, the plaintiff committed suicide just *two months before* FDA issued a press release telling doctors to stop using Paxil to treat pediatric major depressive disorder;[11] in *Dorsett*, the plaintiff committed suicide *two weeks before* FDA "issued a letter to all generic fluoxetine manufacturers, including [the defendant] instructing them to revise their labels to include [a] stronger suicide warning . . . ."[12] And, in *Cross*, FDA requested a labeling change even *before* the plaintiff committed suicide.[13] Beyond these

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[10] *See Dorsett v. Sandoz*, 699 F. Supp. 2d 1142, 1151 (C.D. Cal. 2010) ("Since late 2003, the FDA has been strengthening and refining its warning labels for SSRIs.").

[11] *Mason*, 596 F.3d at 395 ("[I]t seems unlikely that the FDA would have refused to allow GSK to warn about a possible risk of suicide for young adults when it has already warned the public that Paxil was potentially unsafe for 17-year-olds . . . .").

[12] *Dorsett*, 699 F. Supp. 2d at 1151. FDA had already allowed enhanced suicidality warnings for two other SSRIs, Effexor and Paxil. The *Dorsett* court also concluded that "[a] mere possibility that the FDA might not have allowed an enhanced suicidality warning for Prozac, despite allowing it for Effexor and Paxil, is not enough to warrant preemption." *Id.* at 1159. There are no comparable facts here, where FDA has concluded that the scientific evidence does not support such a warning for *any* incretin-based medication.

[13] *Cross*, 2015 WL 1534458, at *4. Plaintiffs dismiss the *Dobbs* decision, which granted summary judgment on preemption grounds, as an "outlier." Pls. MDL Opp. at 7 n.4; *see also* Pls. JCCP Opp. at 18. But *Dobbs* presents the fact pattern most like this case: "Despite the scope of [FDA's] 2006 analysis, . . . [FDA] found no support for a suicidality warning applicable to the age group of which Mr. Dobbs was a member. *To date, it has not done so*." *Dobbs v. Wyeth Pharm.*, 797 F. Supp. 2d 1264, 1275 (W.D. Okla. 2011) (emphasis added).

differences, the overriding difference is that there is no counterpoint in those cases to FDA's "unprecedented" decision here to join with EMA in conducting a comprehensive analysis of the safety data relating to pancreatic cancer, to publish the results in the *NEJM*, and to declare that the data is "adequately reflected in the product information or labeling."

B. Plaintiffs Misapply the "Clear Evidence" Test

Plaintiffs misapply the "clear evidence" test by misstating the evidence. Regarding the Assessment, they do so in three ways. *First*, the 2014 Assessment is indeed an official FDA statement. Only if an "FDA-Assigned" article contains a "disclaimer to emphasize that the views expressed in the article or speech do not necessarily represent the official views or policies of the agency" is it not an official statement of the agency.[14] And the 2014 Assessment did not include any disclaimer. Plaintiffs' expert testified that the Assessment "represents FDA's position."[15]

Second, almost every word of the Assessment belies Plaintiffs' assertion that it was confined to "the Butler group's findings"[16] and did not constitute a comprehensive evaluation of the risk of pancreatic cancer. The Assessment refers to the Butler article in a single sentence and treats it as just one of many items reviewed in its comprehensive analysis. It discusses at length the array of safety data concerning pancreatitis and pancreatic cancer.[17] The article begins with an expression of concern about "post-marketing reports of pancreatitis and pancreatic cancer in patients taking certain antidiabetic medications" and describes the agencies' task broadly as the "evaluation of the postmarketing reports of pancreatic adverse events."

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[14] FDA Staff Manual Guide 2126.3, Review of FDA-Related Articles and Speeches § 6.A (Ex. X to 6/19/2015 Laurendeau Decl.).

[15] Fleming Tr. 84:25 (relevant portions attached as Ex. FF to the 8/7/2015 Declaration of Amy J. Laurendeau ("8/7/2015 Supp. Laurendeau Decl.") (attached hereto)).

[16] Pls. MDL Opp. at 10 (emphasis omitted); *see also* Pls. JCCP Opp. at 14-15.

[17] FDA/EMA Assessment at 795 n.1. The Butler article revealed one possible safety signal, according to the Assessment; postmarketing reports were another.

Regarding the 25 clinical trials reviewed by FDA, the article refers to the agency's focus on any "evidence of an increased risk of pancreatitis or pancreatic cancer." Likewise, regarding the cardiovascular outcome trials and observational studies, the article refers to the agencies' purpose as "explor[ing] a possible association between incretin-based drugs and acute pancreatitis." In conclusion, the article refers to the agencies' exploration of "multiple streams of data pertaining to a pancreatic safety signal associated with incretin-based drugs."[18] To be sure, the Assessment was not a comprehensive evaluation of *all* risks possibly associated with incretin-based drugs, but it was a comprehensive evaluation of the possible risk of pancreatic cancer.

Third, it is irrelevant to the pending motions that FDA "continues to 'evaluate all available data,'" Pls. MDL Opp. at 11, or has "ongoing strategies" to gather additional data. FDA always continues to monitor safety data about these (and all) prescription drugs. The "clear evidence" test is not concerned with what FDA may do in the future, but with what FDA would have done at the relevant time. Thus, here, the question is whether there is clear evidence that FDA would not have approved a pancreatic-cancer warning when Plaintiffs were using incretin-based medications, in most instances *before* 2014.[19]

In any event, one of FDA's "ongoing strategies" to gather additional data was the "systematic capture of data on pancreatitis and pancreatic cancer from cardiovascular outcome trials."[20] What Plaintiffs do not acknowledge is that the results of the first such trial (TECOS) have just been released. They show that the

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[18] *Id.* at 794-96 (collectively, for quotations in this paragraph).

[19] Plaintiffs knock down a straw man when they say that the Assessment was not "a final, conclusive statement." Pls. MDL Opp. at 10, 12; *see also* Pls. JCCP Opp. at 13. Defendants' position is not that, looking to the future, FDA will never say another word on the subject of incretin-based drugs and pancreatic cancer; Defendants' position is that what FDA said in 2014 and in related actions since constitutes "clear evidence" that it would not have approved a pancreatic-cancer warning *then or earlier*.

[20] FDA/EMA Assessment at 796 (Ex. A to 6/19/2015 Laurendeau Decl.).

incidence of pancreatic cancer was *lower* in the sitagliptin group than in the control.[21]

Plaintiffs also misapply the test by employing an obvious fallacy. Rather than consider the evidence taken as a whole, Plaintiffs consider each element separately—FDA's initial approval of the labeling; its 2014 Assessment; its subsequent denial of the Victoza Citizen's Petition; its approval of Saxenda, etc.—and argue that each is insufficient on its own. Pls. MDL Opp. at 8-15; Pls. JCCP Opp. at 13-18. The "big picture" is that everything FDA has said and done since the Assessment reflects that its view remains the same. To begin, FDA in March 2014 denied a Citizen's Petition to remove Victoza from the market, finding that the Petition offered "no new evidence regarding the risk of pancreatic carcinoma . . . that would support any changes to the current approved labeling."[22] Plaintiffs attempt to dismiss this conclusion by saying (rather disingenuously) that the Petition did not "request[]" a pancreatic-cancer warning. Pls. MDL Opp. at 13; Pls. JCCP Opp. at 16. But the Petition went much further, requesting the drug's removal from the market altogether based on an alleged pancreatic-cancer risk (among other things). Plaintiffs inexplicably ignore FDA's statement that nothing said in the Petition warranted a pancreatic-cancer warning.

Then, in September 2014, FDA prepared a Briefing Book for the Advisory Committee assessing Saxenda and told the Committee that the scientific evidence reviewed by the agency "do[es] not support pancreatic cancer as an incretin mimetic-mediated event."[23] Plaintiffs complain that the Briefing Book contains a disclaimer.

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[21] Jennifer B. Green et al., *Effect of Sitagliptin on Cardiovascular Outcomes in Type 2 Diabetes*, N. Engl. J. Med. 373:3, at 238, Table 1 (July 16, 2015) (Ex. EE to 7/17/2015 Supp. Laurendeau Decl.).

[22] Letter from Janet Woodcock, Dir., FDA Ctr. for Drug Evaluation & Research, to Elizabeth Barbehenn & Sidney M. Wolfe, at 26, 37 (Mar. 25, 2014) ("Public Citizen Letter") (Ex. B to 6/19/2015 Laurendeau Decl.). Plaintiffs' claim that "FDA's response is silent on whether the manufacturer would be forbidden to add a warning by CBE," Pls. JCCP Opp. at 16, cannot be squared with the agency's express affirmation of the current warning in rejecting the Petition.

[23] FDA Briefing Document, NDA 206321, at 313 (Sept. 11, 2014) ("Saxenda Briefing Book") (Ex. C to 6/19/2015 Laurendeau Decl.).

Pls. JCCP Opp. at 17. But this objection amounts to little more than a quibble, because FDA in the end approved Saxenda without requiring a pancreatic-cancer warning.[24] Thus, even if the Briefing Book did not represent FDA's final position, the approval of Saxenda does. In both, FDA was consistent in finding that the scientific evidence does not support a pancreatic-cancer warning.

At public conferences and in internal memoranda, FDA personnel have made statements consistent with the Assessment, the denial of the Citizen's Petition, and the approval of Saxenda. Plaintiffs say that these statements "lack the force of law." Pls. MDL Opp. at 15. The importance of these consistent statements, however, is not that they constitute legal commands but that they contribute to the body of clear evidence that FDA would not have approved a pancreatic-cancer warning.[25]

Plaintiffs try to walk back Dr. Fleming's admission that the FDA/EMA Assessment is truly "unprecedented" in two ways. *First*, they make a straw-man argument that it is Defendants' position that FDA must merely give "more than passing attention" to an issue to satisfy *Wyeth v. Levine*. *See* Pls. MDL Opp. at 4; *see also* Pls. JCCP Opp. at 18-20. Defendants' actual argument is that "passing attention" is *all* FDA gave to the alleged risk in *Wyeth*, whereas here FDA completed a comprehensive analysis of the contested issue, including conducting its own studies, and publicly issued a conclusion that the labeling is adequate as is. *Second*, Plaintiffs make the odd argument that the Court should give greater weight to FDA's 2013 Drug Safety Communication (in which the agency said that it was "continuing to evaluate all available data to further understand this potential safety issue") than to the 2014 Assessment, which constituted the promised evaluation of "all available data." *See*

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[24] *See* Defs.' Opening Brief (filed 6/19/2015) at 7.

[25] The statement by FDA's Dr. Graham quoted by Plaintiffs only confirms Defendants' argument that FDA continues to pay close attention to the possible risk of pancreatic cancer. Pls. MDL Opp. at 15. Notably, the approval of Saxenda *post-dates* his statement. *See* FDA Approval Letter for Saxenda (Ex. Q to 6/19/2015 Laurendeau Decl.).

Pls. MDL Opp. at 11-12; Pls. JCCP Opp. at 13-14. The Assessment supersedes the earlier Communication.

As for the argument that FDA must consider all the data and that Defendants withheld data from FDA, Plaintiffs ignore the MDL Court's prior rulings. The MDL Court has held already that "allegations of misreporting or under-reporting . . . [are not] relevant to a preemption analysis" and that "the absence of or mis-characterization of data due to alleged FDA reporting violations is not within the purview of the Court."[26] Additionally, these data are not relevant for the reasons set forth at greater length in Defendants' recent opposition to Plaintiffs' summary judgment motion. Defs. Opp. at 13-17. Even were these data relevant, there is no expert evidence (or any evidence) in the record to support the claim that any of the omitted data is material (i.e., would have changed FDA's conclusion about the risk of pancreatic cancer). Nor is there any evidence that FDA regulations required Defendants (or any of them) to disclose all the data cited by Plaintiffs. FDA regulations define precisely what data manufacturers should submit[27]—guidance designed to ensure that FDA is not flooded with irrelevant or cumulative data. "New safety information arrives every day," just as Plaintiffs say. Pls. JCCP Opp. at 24.

Conclusion

This case presents unprecedented, and undisputed, facts reflecting FDA's attention to the very allegations of risk and failure to warn raised in Plaintiffs' complaint, combined with FDA's conclusion that the labeling is adequate in light of current knowledge. Those undisputed facts more than satisfy *Wyeth*'s demanding "clear evidence" test.

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[26] Order Denying Plaintiffs' Motion to Compel Discovery of Adverse Event Source Documents [ECF 705] at 3-5 (Ex. GG to 8/7/2015 Supp. Laurendeau Decl.); *see also* Order Denying Plaintiffs' Motion for Reconsideration [ECF 833] at 3-4 (Ex. HH to 8/7/2015 Supp. Laurendeau Decl.).

Dated: August 7, 2015

Respectfully submitted,

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SIGNATURE ATTESTATION

Pursuant to Section 2.f.4 of the Court's CM/ECF Administrative Policies, I hereby certify that authorization for the filing of this document has been obtained from each of the other signatories shown above and that all signatories have authorized placement of their electronic signature on this document.

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